K030375

510(k) Summary of Safety and Effectiveness
(As described in 21 CFR 807.92)

MAY 05 2003

I. Trade Name: **Soft-Touch™ TENS electrode**

Sponsor: Pain Management Technologies, Inc.
43 E. Market St.
Akron, OH 44308
Registration No. 1528161

Device Generic Name: Electrode Cutaneous

Classification: Class II
Product Code: 84gxy

Predicate Devices: The k915333 and the k912643 electrodes

II. Indications for use:
The PMT Soft-Touch™ external TENS Electrodes are indicated for use with transcutaneous electrical stimulation devices as a non-sterile, disposable device for single patient use only. The PMT electrodes provide the conductive interface between the TENS generator and the patient's skin.

The PMT TENS electrode Soft-Touch™ are designed for, and to be used with marketed and FDA approved TENS stimulators.

III. Device/Product Description: The PMT Soft-Touch™ electrodes are high quality carbon electrodes.

IV. Contraindications, Warnings, and Precautions:

Contraindication:

Electrodes must not be used for stimulation on persons with cardiac demand. Pacemakers, implanted defibrillators, or other implanted metallic or electronic devices.

Warnings:

- The long-term effects of prolonged use of cutaneous electrodes for electrical stimulation are unknown.
- Electrodes should not be applied over the neck. Severe spasm of the muscle: may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing. Stimulation using electrodes placed over the neck could also have adverse effects on the heart rhythm or blood pressure.
- Electrodes should not be applied across the chest because the introduction of electrical current into the chest may cease rhythm disturbances to the heart.
- The effects of stimulation of the brain are unknown. Therefore, electrodes should not be placed on opposite sides of the head. Electrodes should be applied only to normal, intact, clean akin. Electrodes should not be applied over open wounds or over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Electrodes should not be applied over, or in proximity to, cancerous lesions.
- Electrodes should not be shared with other persons. Each person should have their own set of electrodes; otherwise, undesirable skin reactions may occur.

- Self-adhesive electrodes should be replaced if they no longer stick firmly to the skin.

Precautions:

- Some persons may experience skin irritation or hypersensitivity due to the electrical stimulation, the electrode materials, or the electrical conductive medium (gel).
- Electrodes should be kept out of reach of children.
- The size, shape, and type of the electrodes may affect the safety and effectiveness of your electrical stimulation treatments. Using electrodes that are too small could result in discomfort or skin burns. Contact the manufacturer of the electrical stimulator if you do not know if the electrode can be used in your treatment.

Adverse Reactions:

- Skin irritation and burns beneath the electrodes have been reported with the use of electrodes applied to the skin.
- Headache and other painful sensations have been reported during or following the application of electrical stimulation applied to the head, face, and near the eyes.

V. Alternative Practices and Procedures: N/A

VI. Marketing History: Refer to Attachment 1

VII. Potential Adverse Effects of the Device on Health: If the device is used improperly or for extended periods without replacement, then there is a Possibility for minor burns.

VIII. Summary of Pre-clinical Studies, Laboratory studies, Animal studies, and Additional studies: Refer to NAMSA Reports (Attachments 3, 4, 5)

IX. Summary of Clinical Studies Study design, Patient assessment, Demographic data, Data analysis, and result Device failures and replacements: Refer to NAMSA Reports (Attachments 3, 4, 5).

X. Conclusions drawn from the Studies, Risk/benefit analysis, Safety Effectiveness: Refer to NAMSA Reports (Attachments 3,4,5) Safety and Performance: Substantial equivalence for this device was based on similarities in design and performance characteristics as well as performance testing. The Materials, performance specifications and essential design characteristics of the PMT Soft-Touch™ electrodes are equivalent to those of predicate devices.

Conclusion:
Based on the indications for use, technological characteristics, and in comparison to predicate devices, the PMT Soft-Touch™ electrodes have shown to be safe and effective for its intended use.

XI. Panel Recommendations
XII. CDRH Decision

K030375

Approval Specifications

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 5 2003

Mr. Joshua Lefkovitz
Pain Management Technologies, Inc.
43 East Market St.
Akron, OH 44308

Re: K030375
Trade/Device Name: Soft-Touch ™ TENS Electrodes - sizes 1.5 " square, 2 " round, 2 " square, 3 " round, 1.5 " x 3.1 ", 1.5 " x 6 ", and 4" x 6"
Regulation Numbers: 21 CFR 882.1320
Regulation Names: Cutaneous electrodes
Regulatory Class: Class II
Product Codes: GXY
Dated: January 8, 2003
Received: February 4, 2003

Dear Mr. Lefkovitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PMT, Inc.
510(k) submission
Cutaneous Electrode,

Indications for Use Statement

510k Number: K030375

Device Name Indication for use:

Indication for Use:

The PMT Soft-Touch™ external TENS Electrodes are indicated for use with transcutaneous electrical stimulation devices as a non-sterile, disposable device for single patient use only. The PMT electrodes provide the conductive interface between the TENS generator and the patient's skin.

The PMT TENS electrode Soft-Touch™ are designed for, and to be used with marketed and FDA approved TENS stimulators.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030375